REMARKS

Claims 41-59 are pending. Claims 41-45 and 47-50 have been amended; claims 46 and 51-59 have been cancelled; and claims 60-90 have been added. No new matter has been added.

Claims 41-59 stand rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 5,197,963 to Parins ("Parins"). The applicants submit that this rejection is overcome by the amendments to the claims. The applicants provide the following remarks to clarify several points regarding Parins, based on statements that appeared in the July 24, 2002, Office Action. Specifically, the Office Action stated at page 3, lines 1-2, that as "seen in figures 4 and 5 there is further disclosed an aspiration aperture (108/106) which the first and second electrodes extend across."

With respect to figure 4 of Parins, the applicants submit that neither of electrodes 96 and 98 extend across aspiration aperture 106. Figure 4 clearly shows that electrode 96 does not extend even partially across aspiration aperture 106 because electrode 96 does not overlap any portion of aspiration aperture 106. Electrode 98 is further away from aspiration aperture 106 than electrode 96 and, therefore, also does not extend even partially across aspiration aperture 106.

With respect to figure 5 of Parins, the applicants submit that figure 5 itself discloses only a single electrode 122. Although Parins states that the embodiment of figure 5 may be included on a bipolar instrument (col. 5, lines 8-12), there is no suggestion that a second electrode would extend across the aspiration aperture. Indeed, the placement of electrodes 96 and 98 in figure 4 suggests that a second electrode in the embodiment of figure 5 would not extend across the aspiration aperture. Further, the geometry and placement of Parins's disclosed electrodes (figures 3-5) suggests that no more than one electrode could extend across the aspiration aperture.

Accordingly, Parins does not teach or suggest "the first electrode being an active electrode and the second electrode being a return electrode, wherein . . . each of the first and second electrodes has a portion extending across the aspiration aperture" (amended claim 41).

The applicants have also amended the specification and the drawings. No new matter has been added.

Attached is a marked-up version of the changes being made by the current amendment.

The applicants thank the Examiner for the return of the initialed PTO Form-1449 sheets. The applicants note that the references on one sheet (labeled 5 of 5 and listing two literature documents) were not initialed, and respectfully request that the references listed on this sheet (copy attached) be initialed and returned.

The applicants ask that all claims be allowed. Enclosed is a $1,458.00 check for excess claim fees ($528) and for the Petition for Extension of Time fee ($930). Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the specification:

Paragraph beginning at page 3, line 19, has been amended as follows:

These and other objects and features are accomplished in accordance with the principles of the present invention by providing a probe having a cannula with at least one electrode for the transmission and application of energy to a treatment site along an energy application surface as well as a suction lumen through which unwanted matter and surgical by-products may be aspirated from the treatment area. Preferably, at least one electrode, an active electrode is provided on a distal end of the probe. A return or indifferent electrode may be located on the [patients'] patient's body or on the probe. The instrument is coupled to an energy generator that [preferable] preferably includes controls that may be used to regulate the power, frequency, and voltage applied to the instrument to vary the type of treatment for which the instrument is used. The regulation may include feedback controls.

Paragraph beginning at page 6, line 7, has been amended as follows:

FIGS. 18A-C are cross-sectional, end, and perspective views of an alternative embodiment of the distal tip having a single aspiration opening with both active and return electrodes formed by loop prongs defining the energy application surface;

Paragraph beginning at page 7, line 28, has been amended as follows:

Electrodes 22 and 24 are electrically isolated from each other such that electrical arcing between active electrode 22 and return electrode 24 generates treatment energy along energy application surface 20 that may be applied to the patient. Electrical isolation or insulation of electrodes 22 and 24 at energy application surface 20 may be accomplished by the provision of insulator 28 therebetween. Insulator 28 is formed from [many] any desired insulative material, such as ceramic, [teflon] Teflon or pyrolytic carbon, that may withstand the high temperatures that may result upon application of energy at distal end 12 during use of the instrument 10. Preferably, active electrode 22, return electrode 24, and insulator 28 permit fluid communication

through instrument 10 from the treatment area at which energy application surface 20 is applied to proximal end 14, as described in further detail below.

Paragraph beginning at page 8, line 4, has been amended as follows:

In addition, electrodes 22 and 24 must also be electrically isolated axially along longitudinal axis 11 between proximal end 14 (at which instrument 10 applies treatment energy) so that power [supply] supplied to energy application surface 20 is not shorted. Although insulation on wire 26 is typically sufficient to electrically insulate active electrode 22 from return electrode 24, optional insulation 30 on interior surface 32 of return electrode 24 may be provided. Insulation 30 is selected from biocompatible and electrically insulative material which could include nylon, polyimide, or other shrink tubing and also functions to limit the heat transfer to the shaft. If active electrode 22 (rather than return electrode 24) is coupled to the power source via a conductive shaft as mentioned above and described with respect to the embodiments of FIGS. 8-11, insulation 30 would be more desirable. An insulative cover 34, such as formed from a [teflon] Teflon coating or a heat shrink cover, is provided over exterior surface 36 of return electrode 24 to restrict the extent of arcing and hence energy supplied to distal treatment end 12 of instrument 10.

Paragraph beginning at page 8, line 24, has been amended as follows:

Electrosurgical aspiration instrument 10 may be used for a variety of electrosurgical treatments. [On] One particular use of instrument 10 is for ablation of human or animal tissue. Because ablation generally occurs at very high temperatures, e.g., 300-1000 degrees Celsius, some and/or vapor may be generated during ablation. It may be desirable to remove smoke; unwanted or excess gases, such as air bubbles; fluids, such as irrigation fluid required to irrigate or enhance conduction after treatment; from the treatment area during treatment. Moreover, debris or other materials or biological elements may remain after the ablation procedure that should be removed from the treatment area. Thus, in accordance with the principles of the present invention, instrument 10 is also designed to aspirate such unwanted matter from the treatment area during the electrosurgical procedure performed thereby. It will be appreciated that aspiration may be performed either simultaneously with, before, or after electrosurgical

treatment of an area. Further, it should be appreciated that a power source may be used which sequentially, or in a predetermined sequence, supplies power to the active electrode and then provides power for aspiration. Accordingly, an aspiration lumen 50 is provided within electrosurgical aspiration instrument 10 along longitudinal axis A-A. Aspiration lumen 50 may be formed by interior wall or surface 32 of return electrode 24 and is in fluid communication with [a] an aspiration line 52 which couples proximal end 14 of instrument 10 with a vacuum source [of] or other aspiration device (not shown). Aspiration line 52 is preferably standard tubing for connection to a suction source and device.

Paragraph beginning at page 9, line 9, has been amended as follows:

In order to facilitate aspiration during electrosurgical treatment, such as during ablation or coagulation, instrument 10 is provided with an aspiration means which permits aspiration through energy application surface 20. This is accomplished by providing at least one through-hole or aperture 25 through active electrode 22 which defines surface 20. Alternatively, a plurality of through-holes or apertures through active electrode 22 may be used to aid in aspiration of the electrosurgical probe. In the embodiment of FIGS. 1 and 2, active electrode 22 is in the form of a wire mesh or screen 22A supported by an electrically conductive ring 22B. Mesh 22A and ring 22B comprising active electrode 22 are formed from [a] conductive materials, such as stainless steel, tungsten, or titanium, or their alloys, that can withstand the high temperatures resulting from use of instrument 10. The entire mesh [and ring] of active [electrodes] electrode 22 serves as the energy application surface and is powered by the power supply so that the electrosurgical application, such as ablation, occurs over the electrode. Thus, the active aspiration is approximately co-extensive with energy application surface 20. The preferred range of mesh sizes is from approximately 30 mesh to approximately 55 mesh.

Paragraph beginning at page 10, line 6, has been amended as follows:

Moreover, in the present embodiment, return electrode 24 is located on shaft 27 proximal to active electrode 22. This defines a unipolar configuration where the return electrode 24 has a larger surface area than active electrode 22, functions as an indifferent return to the power source, and the energy is diffuse around electrode 24. This provides the active electrode 22 with

a higher current density such that treatment energy is crowded and the treatment effect is generally in the area of tissue in proximity to active electrode 22. In an alternative embodiment, however, return electrode 24 may be located on a surface on the patient's body in the form of a grounding plate or pad. In this configuration, the return electrode functions to return the treatment energy to the power source to define a monopolar configuration.

Paragraph beginning at page 11, line 30, has been amended as follows:

The arrangement and electrical connections of electrodes 522 and 524 of electrosurgical instrument 510 may be appreciated with reference to FIG. 7. It will be understood that a similar arrangement may be used for electrosurgical instruments 510 and 610 as well. In the exemplary embodiment, FIG. 7 illustrates a cross-section through shaft 727 showing electrical power conductor 716, in the form of a wire extending [proximally] distally from a power source (not shown) located at proximal end 714 to distal end 712 of instrument 710. Power conductor 716 passes through lumen 750 and provides power to central electrode 722. Electrical power conductor 736 is in the form of shaft 727 being electrically conductive and conductor 736 electrically coupled to return electrode 724 via extension 736. Electrical conductors 716[, 726,] and 736 are electrically isolated from each other in any desired manner, such as [in] with insulative material such as interior insulation 730 in a manner described above. An insulative coating or covering 734 is provided on the exterior surface of instrument 710, preferably to protect the patient from any energy discharge conducted through electrical conductor 736.

Paragraph beginning on page 12, line 15, has been amended as follows:

It should be appreciated that the active electrode in FIGS. 5-7 can be sized appropriately, relative to the return electrode or vice versa, such that application or power to the active electrode and use of the electrosurgical instrument approximates the effect delivered by a bipolar electrosurgical instrument. In a typical bipolar instrument, both electrodes are of the same size and approximately located [with in] within the same proximity such that both electrodes equally affect the tissue area to which the instrument is applied. By sizing the active electrode and the return electrode to be of approximately equivalent sizes, a bipolar effect may be achieved with the present invention. It should be further appreciated that it is possible to size the electrodes in

any of the embodiments of the present invention so as to achieve a bipolar effect. The return electrode of the present invention may also be located on the patient's body as discussed above.

Paragraph beginning on page 13, line 31, has been amended as follows:

FIGS. 9A and 9B illustrate another alternative embodiment of electrosurgical instrument 810 having an active electrode 922 in the form of a ring electrode on distal tip 812. The ring electrode configuration of active electrode 922 may be preformed memory metal or a solid metal tip on distal tip 812. Electrode 922 is formed of any biocompatible material including stainless steel, tungsten, titanium, or any of [its] their respective alloys.

Paragraph beginning on page 14, line 23, has been amended as follows:

FIGS. 10A and 10B illustrate another alternative embodiment of electrosurgical instrument 810 having an active electrode 1022 in the form of a double prong on distal tip 812. The double prong configuration of active electrode 1022 may be preformed memory metal or a solid metal partial loop or coil on distal tip 812. Electrode 1022 is formed of any biocompatible material including stainless steel, tungsten, titanium, or any of [its] their respective alloys.

Paragraph beginning on page 15, line 10, has been amended as follows:

FIG. 10B is an end view of the distal tip of the instrument of [Fig.] FIG. 10A. Active electrode 1022 is shown as a prong passing over aperture 825. In this embodiment, two prongs pass over the aperture 825 to prevent blockage of the aperture. Both electrode prongs are electrically connected to the power source through a single conductor 816 such that equal power is transmitted to active electrode 822 at the same time for equal effect. It will be appreciated that any number of prongs and [the] configurations may be [use] used. Return electrode 824 is shown within the aspiration lumen and is electrically isolated from the active electrode 922 by insulator 828.

Paragraph beginning on page 15, line 29, has been amended as follows:

An alternate embodiment of the active electrode as shown in FIG. 11B is similar to the electrosurgical aspiration instrument of FIG. 11A where like elements are described with the

same reference numbers. In this configuration, active electrode 1122 has cutouts 1129 to form a grating surface with cutout edges 1180. By configuring the active electrode with cutout edges, the active electrode 1122 forms high current densities at the energy application surface 1120 such that current is crowded at the edges 1180. Thus, maximum ablation in combination with a mechanical cutting and grating effect is achieved.

Paragraph beginning on page 17, line 4, has been amended as follows:

Return electrode 1224 is located internally within aspiration lumen 1250 to form a boiling chamber as described above. The electrical energy is returned to the power source from return electrode 1224 by return conductor 1226. The return electrode 1224 is electrically [insolated] isolated from active electrode 1222 by insulator 1228.

Paragraph beginning on page 18, line 4, has been amended as follows:

FIGS. 15A-C illustrate different views of ashtray electrode according to one alternative embodiment of the active electrode as described above. Like elements will be referenced by the same reference numbers. FIG. 15A shows a close-up perspective view of active [electrode1522] electrode 1522 in which at least one aperture 1525 is provided through active electrode 1522. Active electrode 1522 is configured to crowd the current creating a high current density along a circumferential edge 1580. Edge 1580 defines energy application surface 1520. Cutouts 1529 form a pattern along edge 1580 to maximize the current crowding. As the current is crowded along edges 1580, a mechanical scraping and ablative effect [occurs] occur simultaneously. Current is also crowded along edge 1580 formed within aperture 1525 to prevent blockage of the aperture. As energy is applied to the active electrode, the sharp edge of surface 1580 provides both a surface for the delivery of RF power for ablation while simultaneously providing a mechanical grating or scraping surface for scraping tissue at the surgical tissue site. It will be appreciated that edge 1580 of electrode 1520 may be rounded such that a smoothing surface may be formed and sculpting may be performed with the instrument of the present invention.

Paragraph beginning on page 20, line 5, has been amended as follows:

It will be appreciated that the above-described arrangements that provide an energy application surface area at the distal tip of the electrosurgical instrument may be applied to an

instrument that is not capable of aspiration. Thus, insulator 1628 of instrument 1610 may be a substantially solid element with passages therethrough for the purpose of electrically coupling electrodes 1622 and 1624 to the power source but not for aspiration purposes. The arrangement of the active and return electrodes may be further modified as in FIGS. 10 and 11 to provide [and] an energy application surface area that, although contoured (i.e., not completely planar), still remains at the distal end of the instrument, substantially transverse to the longitudinal axis, without extending along a distal portion of the side walls of the instrument (such as in instrument 10 of FIGS. 1 and 2).

Paragraph beginning on page 20, line 15, has been amended as follows:

FIGS. 17A and 17B illustrate another embodiment of the electrosurgical aspiration instrument 1710 of the present invention in which the active electrode 1722 and the return electrode 1724 are comparably sized and located in close proximity to each other at the distal end 1712. This arrangement of electrodes 1722 and 1724 define a true bipolar configuration. Active electrode 1722 is a single disc shaped electrode which is centrally located at distal end 1712 within insulator 1728. Return electrode 1724 is a ring electrode located substantially along the same plane at the circumferential edge of insulator 1728. The effective area [size] sizes of both electrodes are similar such that the delivered treatment energy is equal between both electrodes. Apertures 1725 are located within insulator [1828] 1728 and [communicates] communicate with aspiration lumen 1750. As the ablation, cutting, and coagulation occur at the active electrode 1722, the suction applied to the aspiration lumen forces the by-products and excess fluid through apertures 1725.

Paragraph beginning on page 20, line 31, has been amended as follows:

FIGS. 18A-C illustrate a further alternative embodiment of the electrosurgical aspiration instrument 1810 of the present invention in which the active and return electrodes 1822, 1824 lie in the same plane at the distal end 1812. The active and return electrodes are [substantially configured] configured substantially similarly such that the two conductors 1816 and 1826 are electrically coupled through shaft 1827 to the distal end 1812. Electrodes 1822 and [1834] 1824 are electrically isolated by insulator 1828. Delivery of energy is equal to both electrodes such

that an equal, bipolar effect occurs at the surgical site. Both electrodes extend from one side of aspiration aperture 1825 to a point across the aperture and return to the generator. One electrode serves as an active electrode and one electrode serves as a return electrode. It will be appreciated that either electrode may be an active or a return since the polarity of the power generator may be reversed. Because both electrodes are configured across the aspiration aperture 1825, clogging and blockage of the aperture is prevented or reduced.

In the claims:

Claims 46 and 51-59 have been cancelled without prejudice or disclaimer.

Claims 41-45 and 47-50 have been amended as follows:

--41. (Amended) A surgical instrument for treating tissue comprising an elongate probe member having (i) proximal and distal **[extremities]** portions, the distal **[extremity]** portion having a distal surface and first and second spaced-apart electrodes **[protruding from]** coupled to the distal surface and adapted to engage the tissue, and (ii) first and second electrical leads carried by the elongate probe member and extending **[from the proximal extremity]** to the distal **[extremity]** portion, the first and second electrical leads being coupled respectively to the first and second electrodes for supplying electrical energy to the first and second electrodes, the first electrode being an active electrode and the second electrode being a return electrode**[.]**,

wherein the distal surface defines an aspiration aperture and the elongate probe member defines a lumen extending to the aspiration aperture, and each of the first and second electrodes has a portion extending across the aspiration aperture.

42. (Amended) The surgical instrument of **[Claim]** claim 41 wherein at least one of the first and second electrodes has a portion spaced outwardly from the distal surface.

43. (Amended) The surgical instrument of **[Claim]** claim 42 wherein each of the first and second electrodes has a portion spaced outwardly from the distal surface.

44. (Amended) The surgical instrument of **[Claim]** claim 42 wherein the at least one of the first and second electrodes has the shape of a partial loop.

45. (Amended) The surgical instrument of **[Claim]** claim 42 wherein the at least one of the first and second electrodes has the shape of a prong.

47. (Amended) The surgical instrument of **[Claim 46]** claim 41 wherein the portions of each of the first and second electrodes extending across the aspiration aperture **[has a portion]** are spaced outwardly from the distal surface **[and extending across the aspiration aperture]**.

48. (Amended) The surgical instrument of **[Claim]** claim 41 wherein the first and second electrodes extend parallel to each other.

49. (Amended) The surgical instrument of **[Claim]** claim 41 wherein the first and second electrodes extend in the same plane.

50. (Amended) The surgical instrument of **[Claim]** claim 41 wherein each of the first and second electrodes is cylindrical in shape.--